401 KAR 8:700. Bottled water.

RELATES TO: KRS 224.10-100, 224.10-110, 21 C.F.R. 165.110
STATUTORY AUTHORITY: KRS 224.10-100, 224.10-110, 21 C.F.R. 165.110
NECESSITY, FUNCTION, AND CONFORMITY: KRS 224.10-110 directs the cabinet to enforce the administrative regulations adopted by the secretary for the regulation and control of the purification of water for public and semipublic use. The purpose of this administrative regulation is to set out provisions to assure the purity of water, placed in bottles, that will be resold as a food for human consumption or other consumer use. The U.S. Environmental Protection Agency has no federal regulation relating to bottled water. Certain provisions of this administrative regulation are more stringent than the FDA requirements. The cabinet requires that plans, reports, and monitoring results be submitted to the cabinet to ensure that compliance with all public health standards is achieved without more frequent, costly on-site inspections, and that systems monitor for chlorite more frequently to ensure that public health standards are met for any disinfectant residuals.

Section 1. A bottled water system shall comply with the provisions of 401 KAR Chapter 8 with the following exceptions and provisions:

(1) Distribution systems and free chlorine.

(a) Administrative regulations pertaining to distribution systems of a public water system, including provisions for a free chlorine residual, shall not apply.

(b) The requirements of 401 KAR 8:160 and 401 KAR 8:510 shall not apply to a bottled water system, unless specifically included in subsections 5 and 6 of this section

(2) Microbiological sampling. A bottled water system shall conduct microbiological sampling and testing at least once a week. Tests shall otherwise conform to 401 KAR 8:200.

(3) Samples location.

(a) Except as provided in paragraph (b) of this subsection, samples shall be taken after the disinfection of the water and prior to the water being placed in the bottle, with no intervening stagnant storage.

(b) A sample may be taken from a bottle immediately after bottling and before the bottle leaves the plant, if all other sampling procedures are met.

(c) Water located in the line after bottling operations cease shall be flushed before bottling is resumed.

(4) Turbidity sampling. For a bottled water system, regardless of source, turbidity sampling shall be conducted once every four (4) hours the system is in operation. The system may substitute continuous monitoring for grab sampling, with cabinet approval, and may use the turbidity value for every four (4) hours to determine compliance with the turbidity performance criterion. The turbidity level of the system's product water shall be less than or equal to three-tenths (0.3) nephelometric turbidity units NTU, in at least ninety-five (95) percent of the measurements taken each month, and shall never exceed one (1) NTU.

(5) Sampling, MCL, and MRDL for other contaminants.

(a) MCLs.

1. Except for lead and copper, the MCL for a contaminant for which testing is required in this subsection shall be as specified in 401 KAR 8:250, 401 KAR 8:400, 401 KAR 8:420, and 401 KAR 8:510.

2. Lead and copper. The MCL shall be:

a. Lead: 0.005 mg/L; and

b. Copper: one and zero-tenths (1.0) mg/L.

3. Within twenty-four (24) hours of receiving the test results, a bottled water system shall report to the cabinet violations of the MCL for chlorite and bromate and shall immediately stop bottling operations if violations exist.

(b) MRDLs.

1. Except as provided in subparagraph 2 of this paragraph, the MRDL for disinfectants shall be as specified in 401 KAR 8:510.

2. The MRDL for chlorine dioxide shall be as specified in 401 KAR 8:510, Section 3. No two (2) consecutive daily samples shall exceed the MRDL, monitored at the treatment plant after treatment.

3. A bottled water system shall report to the cabinet a violation of the MRDL for chlorine dioxide as soon as possible after learning of the exceedance, and shall immediately take steps to lower the level of chlorine dioxide in the system.

(c) Sampling.

1. A bottled water system shall monitor annually for the following:

a.(i) Contaminants specified in 401 KAR 8:250, 401 KAR 8:400, and 401 KAR 8:420, except as provided in subclause (ii) of this clause.

(ii) A bottled water system that uses as its source a public water system subject to 401 KAR Chapter 8 may, with written approval from the cabinet, substitute the monitoring results of the public water system for the monitoring required by clause a of this subparagraph. The bottled water system shall submit a letter by January 30 of each year, stating that it shall use the annual results of their purchasing system. The system shall include the PWSID of the purchasing system.

b. Lead;

c. Copper;

d. Total trihalomethanes, or TTHMs; and

e. Haloacetic acids, or HAAs;

2. A bottled water system shall monitor for radionuclides annually, according to the procedures in 401 KAR 8:550.

(6) Disinfection.

(a) Disinfection shall be by chlorination, ultraviolet light, ozonation, chlorine dioxide, or other method approved by the cabinet that provides equivalent treatment.

(b) A bottled water system that uses:

1. Chlorine dioxide shall monitor for chlorite daily in the treatment plant; or

2. a. Ozone shall monitor monthly for bromate in the treatment plant; or

b. Alternatively, a system that uses ozone shall monitor annually for bromate in the treatment plant, if the system demonstrates that the average bromide concentration is less than 0.05 mg/L, calculated as a running annual average of monthly bromide samples.

(7) Surface water treatment. Bottled water systems using surface water sources may, with cabinet approval, use treatment techniques that are different from other surface water users, if equivalent treatment is provided.

(8) Maximum contaminant level exception labeling. With approval of the cabinet, bottled water systems may exceed maximum contaminant levels for secondary contaminants for purposes of bottling "mineral water" or other water, if consumers are informed by proper labeling.

(9) Water bottled outside Commonwealth. Water bottled outside Kentucky shall not be subject to this administrative regulation, regardless of its source.

(10)(a) Analyses shall be performed in accordance with methods approved by 401 KAR Chapter 8 or 21 C.F.R. 165.110, in laboratories that are certified to conduct testing pursuant to 401 KAR 8:040.

(b) Monitoring results shall be received by the cabinet no later than the tenth day of the month following the end of the reporting period.

(11) The public notification requirements of 401 KAR 8:070 and the reporting requirements of 401 KAR 8:075 shall not apply to a bottled water system.

Section 2. Failure to Comply. A bottled water system that exceeds a maximum contaminant level or MCL, or a maximum residual disinfectant level or MRDL, or otherwise fails to comply with 401 KAR Chapter 8 shall:

(1) Immediately cease operations;

(2) Notify the cabinet and the Cabinet for Health and Family Services, Department for Public Health; and

(3) Not resume operation without the written approval of the cabinet. (17 Ky.R. 645; eff. 11-15-90; Am. 23 Ky.R. 2614; eff. 5-14-97; 31 Ky.R. 211; 780; eff. 1-4-2005.)